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Long-term effects of nutritional group education for persons at high cardiovascular risk

WANDA J.E. BEMELMANS, JAN BROER,
KARIN F.A.M. HULSHOF, FRANS W. SIERO, JOHAN F. MAY, BETTY MEYBOOM-DE JONG *

Background: Treatment of persons at high risk for coronary heart disease (CHD) should include nutritional counselling, but little is known about the effects of different types of education. Methods: In a quasi-experimental study design the effects of a nutritional education programme (1st year: three group sessions by a dietitian; 2nd year: one group session; 3rd year: additional focus on saturated fat; reinforcement by written nutritional messages annually) (intervention group; n=103) are compared with the effects of a posted leaflet containing standard dietary guidelines (control group; n=163). Participants had hypercholesterolemia (6–8 mmol/l) and at least two other CHD risk factors. Results: After 3 years, no significant differences existed in established CHD risk factors between intervention and control groups (adjusted mean net differences: total cholesterol (0 mmol/l), diastolic blood pressure (–1.1 mm Hg; NS), and body weight (+0.3 kg, NS)). Regarding dietary intake, the intervention group had a lower intake of total (net difference –2.0% of energy, SEM 0.9) and saturated fat (–1.2% of energy, SEM 0.4) and a higher fish (+11 g/day, SEM 4) and vegetables consumption (+21 g/day, SEM 10) during the study period (p<0.05 for all). Conclusion: A nutritional education programme with group sessions changed dietary intake more effectively than a posted leaflet, but no additional positive effects were observed on established CHD risk factors after three years of follow-up.

Keywords: cardiovascular risk, dietary intake, nutritional education, risk factors

Although in recent decades age standardized mortality rates have declined, coronary heart disease (CHD) remains a leading cause of mortality throughout Europe.[1] Furthermore, declining mortality rates have been accompanied by increased absolute numbers of hospital admissions, mainly due to the chronic forms of CHD.[2] Hence, prevention of the development of CHD is of great public health interest. The established risk factors for the development of CHD are, among others, hypercholesterolemia, hypertension, smoking, obesity, a family history of premature CHD or being physically inactive.[3] In addition, lower socio-economic status is associated with increased prevalence of CHD.[4] Besides differences in smoking and exercise habits this association may be partially due to unhealthy food habits.[5]

In primary prevention, the initiation of drug therapy in the treatment of hypercholesterolemia and hypertension depends on the absolute calculated risk of developing CHD.[6] For example, in persons with a calculated risk for a CHD event within 10 years below 20% the prescription of statins is not considered cost-effective. For patients with an elevated serum total cholesterol, and in particular for those with a level (just) below the level where statin treatment is advised, an alternative is needed. This alternative type of therapy should be professional lifestyle counselling in order to change dietary habits and to stimulate exercise. Most patients at high risk for CHD are seen in primary care but well-known barriers for general practitioners in providing nutritional education are lack of time and insufficient nutritional knowledge and skills.[7] Furthermore, the effects of nutritional counselling in a primary care setting may be considered as disappointing in its effect on serum total cholesterol.[8] Nutritional education is often limited to providing a nutritional leaflet without additional reinforcement, while it can be expected that other, more intensive, types of nutritional counselling are more effective.[9]

In November 1997 (baseline; week 0), a nutritional intervention project started in a socioeconomically deprived area with elevated CHD mortality rates in the northeastern part of the Netherlands. All participants had hypercholesterolemia and at least two other risk factors, but none of the participants used cholesterol lowering drugs at baseline. The study investigated the effects of a nutritional education programme, which involved group sessions by a research dietician (intervention) compared to a posted leaflet containing nutritional guidelines (control) on CHD risk factors and dietary intake after 3 years of follow-up.

MATERIALS AND METHODS

Study design and population

The present study was conducted within the context of a CHD prevention project for persons at high cardiovascular risk (*n*=266), called the MARGARIN project, an acronym of Mediterranean Alpha-linolenic enRiched Groningen dietARy INtervention. The baseline data were collected in November 1997, and follow-up investigations were organized after 16 weeks, and 1, 2, and 3 years. The investigations consisted of blood collection, assessment of blood pressure and weight, and several questionnaires. During two-week periods all participants were investigated at the local hospital in the early morning after an overnight fast.

The MARGARIN study investigated the effects of two different types of nutritional education in a quasi-experimental study design. The intervention group (I group) received nutritional education in group sessions that focused on a Mediterranean type of diet (*n*=103). The control group (C group; *n*=163) received a posted leaflet, that can be compared with the 'care as usual' as provided by the general practitioner. To minimize crossover of information, group I participants were recruited in one county and group C participants were recruited in neighbouring counties.

In addition, during the first two years of the project all participants (both I and C groups) received two types of margarine in

* W.J.E. Bemelmans[1], J. Broer[2], K.F.A.M. Hulshof[3], F.W. Siero[4], J.F. May[5], B. Meyboom-de Jong[1]
1 Department of General Practice, University of Groningen, The Netherlands
2 Municipal Health Service Agency, city of Groningen
3 TNO-Nutrition and Food Research Institute, Zeist
4 Department of Social Psychology, University of Groningen
5 Department of Cardiology, Groningen University Hospital, The Netherlands
Correspondence: Dr. W.J.E. Bemelmans, National Institute for Public Health and the Environment, Department of Chronic Diseases Epidemiology, PO Box 1, 3720 BA Bilthoven, The Netherlands, tel. +31 30 274 3244, e-mail: wanda.bemelmans@rivm.nl

a double blind fashion. The margarines had an equally high amount of polyunsaturated fat (about 60%), but differed according to alpha-linolenic and linoleic acid contents. The results of the margarine intervention have been described in detail elsewhere.[10] In short, after 2 years the effects on serum total cholesterol, blood pressure, and BMI were similar, but the alpha-linolenic acid margarine decreased serum HDL cholesterol level by 0.05 mmol/l or more.

Inclusion criteria for the MARGARIN project were a mean of two serum cholesterol measurements between 6 and 8 mmol/l, together with at least two of the following CHD risk factors: high blood pressure (diastolic ≥95 mm Hg and/or systolic ≥160 mm Hg or use of antihypertensive medication), body mass index (BMI) ≥27 kg/m^2, smoking, diagnosis of CHD, or a first degree relative with a CHD history prior to the age of 60 years. Exclusion criteria were an age below 30 or over 70 years, diabetes mellitus, hypothyroidism, and use of aspirin, anti-coagulant, or cholesterol-lowering drugs. During 1997, potential participants with at least two CHD risk factors were invited for a serum cholesterol measurement. The recruitment procedures are described more extensively elsewhere.[10] The medical ethical committee of Groningen University Hospital approved the study design, and written informed consent was obtained from 282 persons. Before baseline examinations 14 persons dropped out. Further, two persons were excluded because of diabetes mellitus, discovered at baseline examination. After 3 years, 78% of the I group and 73% of the C group were still involved in the study. Reasons for withdrawal were medical reasons (I group n=9, C group n=5), other reasons, e.g. lack of interest or personal problems (I group n=7, C group n=17), and unknown (I group n=7, C group n=22).

Measurements and laboratory analyses

In fasting samples, serum total cholesterol was determined by enzymatic methods on a Vitros 950 (Ortho-Clinical Diagnostics, Rochester NY, USA). Blood pressure was measured in the sitting position by an automatic device. Bodyweight was measured without shoes and heavy clothing. Height was measured at the first follow-up investigation, 16 weeks after baseline, and was considered to be equal during the study period. A standardized medical questionnaire was used to establish presence of cardiovascular disease, family history of CHD, smoking habits, and exercise. Dietary intake was assessed by a self-administered semi-quantitative food frequency questionnaire. Intakes of energy, macronutrients and dietary fibre were validated with a 3-day (non-consecutive, including one weekend day) 24h-recall method in a pilot study within the study population (n=43). Pearson correlation coefficients were as follows (p<0.01): energy intake (r=0.76); total fat as percentage of energy (r=0.66); SFA (r=0.51); MUFA (r=0.52); PUFA (r=0.70); alcohol (r=0.72); and fibre in grams per day (r=0.74). This indicates a reasonable validity and correlation coefficients are comparable with those reported in other research.[11]

Content of dietary educational intervention programme

In general, nutritional education is most effective when it is behaviourally focused and has an appropriate theoretical basis.[9] In the MARGARIN study, the intervention was based on the Fishbein and Ajzen model for planned behaviour and on Prochaska's stages of stage model. The Fishbein and Ajzen model was applied to different types of behaviour, e.g. increasing consumption of fish, fruits and vegetables,[12] slimming behaviour, reducing saturated fat intake, and increasing physical activity. Baseline measurements of the variables for each behaviour, such as positive and negative outcomes, attitude, social norm, and self-efficacy underpinned the content of the educational programme. At all investigations, participants completed a questionnaire on several intermediate effect parameters fitting within these two theoretical concepts (described in detail elsewhere[12]).

The I group was divided into subgroups of 10 participants. Participants and their partners were invited for three meetings of two hours each, which were organized in February and March 1998. The first session discussed risk factors for CHD and the role of a healthy (quasi)-Mediterranean diet. The second session intended to establish a positive attitude towards a healthy food pattern, by discussing positive and negative aspects (beliefs). The third session aimed to improve skills in preparing a 'quasi-Mediterranean diet' (influencing self-efficacy expectations, e.g. by providing recipes and by showing a short video film about healthy (Mediterranean) products for reasonable prices available in two local supermarkets. Four booklets with core information of the educational programme were handed out and sent to participants who did not attend the meetings. The specific nutritional guidelines of the intervention programme were a daily consumption of 5–7 slices of bread, 200–400 grams of vegetables, two pieces of fruit, two to three dairy products, fish twice a week at dinner, less red meat, less fat cheese, and less eggs. Two alcoholic drinks per day were allowed, when persons were already regular alcohol consumers. The use of the project margarines was encouraged during the first two years of the project. In the second year of the MARGARIN project, in March 1999, a single group session focused on reduction of body weight. In the third year (in 2000), 50% of the I group were contacted twice by telephone for dietary advice, which focused on reducing saturated fat intake. Finally, the educational messages were reinforced by written correspondence annually (see *table 1* for a complete time schedule of the educational programme).

The effects of this educational programme (I group) were compared with the C group. In February 1998, the C group received a posted leaflet with the standard Dutch guidelines for a healthy diet. These guidelines differed a little from those that the I group received because the advice on consumption of vegetables was 150 to 200 g/day and, at that time, the Dutch guidelines did not include specific advice on fish consumption.

Statistics

At baseline, differences between I and C groups were analysed for significance (p<0.05) using unpaired Students t-test or analyses of covariance (with gender as a covariate) for normally distributed continuous variables, and the chi-square test for categorical variables.

Analysis-of-covariance techniques were used to analyse the differences between I and C groups in changes of CHD risk factors and dietary intake during the study. We used one-factor ANOVA with type of education as main effect, and as covariates we entered gender and the baseline value. In the analyses of serum lipids and estimated CHD risk users of lipid-lowering drugs during the study were excluded. For *table 4* we used one-factor ANOVA with attendance at the three educational meetings (<two times or ≥two times) as main effect, and gender, age, and the baseline value as covariates.

RESULTS

Baseline

Table 2 shows the baseline characteristics for the I and C groups. The I group had a lower proportion of men (37%) than the C group (49%) (p<0.05), and the I group contained more users of antihypertensive medication (57%) than the C group (43%) (p<0.05). Regarding the other CHD risk factors and dietary intake, no significant differences existed between I and C groups at baseline.

Changes in cardiovascular risk factors and dietary intake during the study

After 3 years no significant differences existed in CHD risk factors between I and C groups (*table 3*). Adjusted mean net

differences between I and C groups were as follows: total cholesterol (0 mmol/l, SEM=0.11; NS), diastolic blood pressure (–1.1 mm Hg, SEM 1.8; NS), and body weight (+0.3 kg, SEM 0.6; NS). When compared to baseline, within the I group serum total cholesterol decreased by 4%, diastolic blood pressure remained equal, body weight increased by 2%, and the estimated CHD risk decreased by 2%, when corrected for increased age during the study period.

Regarding dietary intake the I group had a significantly lower intake of total (net difference = –2.0% of energy, SEM 0.9; $p<0.05$) and saturated fat (–1.2% of energy, SEM 0.4; $p<0.01$), and a higher consumption of fish (+11 g/day, SEM 4; $p<0.01$) and vegetables (+21 g/day, SEM 10; $p<0.05$) than the C group, when adjusted for baseline intake and gender. After 3 years, 26% of the I group and 10% of the C group had a SFA intake below 10% of energy (p of difference between I and C groups <0.05 with χ^2-test).

Effects of attendance of the educational meetings

Of the I group, 68% of men and 78% of women attended at least two educational meetings in the first year of the study (= 'attenders'). The attenders (n=77) were older than the non-attenders (n=26) (mean ages 57 and 51 years, respectively; $p<0.05$). In general, attendance at the meetings did not result in more favourable effects on CHD risk factors or dietary intake, except for a greater reduction of serum total cholesterol (p=0.07) (*table 4*). It should be noted that the number of non-attenders was small.

Table 1 Time schedule of the MARGARIN study

Time period		Activity
1997	January–October	Recruitment of participants
	November (0 weeks)	Baseline examinations + start of margarine provision
1998	February–March	Intervention group: three nutritional education meetings Control group: posted leaflet
	March (16 weeks)	1st follow-up examinations
	September	Intervention group: nutritional education message by mail
	November (1 year)	2nd follow-up examinations
1999	March	Intervention group: group education (weight control)
	September	Intervention group: nutritional education message by mail
	November (2 years)	3rd follow-up examinations + end of margarine provision
2000	March	Intervention group + Control group: written information about replacement of margarines Intervention group: nutritional education message by mail
	September	Intervention group (50%): advice to reduce saturated fat intake (by telephone)
	November (3 years)	4th follow-up examinations

Table 2 Baseline characteristics for intervention and control groups

		Intervention group n=103		Control group n=163	
Variable		Mean	(SD)	Mean	(SD)
Age	(years)	55	(10)	54	(10)
Gender	(% men)	37		49*	
Serum total cholesterol	(mmol/l)	6.8	(0.7)	6.7	(0.8)
Systolic blood pressure	(mm Hg)	146	(23)	144	(22)
Diastolic blood pressure	(mm Hg)	88	(14)	86	(16)
Use of antihypertensive drugs	(%)	57%		43%**	
Present smoking	(%)	47%		51%	
Body mass index	(kg/m^2)	29.8	(3.9)	29.8	(4.8)
Calculated CHD risk[a]	(%)[b]	15.7	(0.8)	15.2	(0.6)
Dietary intake		n=100		n=161	
Energy	(MJ/d)[b]	10.2	(0.3)	10.2	(0.2)
Total fat	(% energy)[b]	37.7	(0.7)	38.2	(0.5)
Saturated fatty acids	(% energy)[b]	14.0	(0.3)	14.3	(0.3)
Dietary fibre	(grams/d)[b]	26.9	(0.8)	27.3	(0.6)
Fish	(grams/d)[b]	19	(3)	24	(2)
Fruit	(grams/d)[b]	265	(17)	268	(14)
Vegetables	(grams/d)[b]	140	(7)	144	(5)
Bread	(grams/d)[b]	159	(7)	158	(5)

Difference between intervention and control groups: * p<0.05, ** p<0.01

a: CHD: coronary heart disease, according to the Framingham risk calculation, based on systolic blood pressure.[13]

b: Adjusted for gender

DISCUSSION

The MARGARIN project showed that nutritional education in groups changes dietary behaviour more effectively than a posted leaflet after 3 years of follow-up. However, this did not result in a more healthy cardiovascular risk profile. During the 1990s, two secondary prevention studies prescribed guidelines resembling a 'Mediterranean type of diet', and these studies showed large reductions in total and CHD mortality (up to 70%).[14,15] The main characteristics of this type of diet are low intake of saturated fat, and high consumption of fruits, vegetables, and oleic acid (olive oil). The dietary guidelines of the present MARGARIN study were based on this quasi-Mediterranean diet. However, due to the free provision of research margarines during the first two years, which contained a large amount of polyunsaturated fat, the educational programme did not focus on oleic acid (olive oil) intake.

Although the provision of research margarines stopped after two years, this intervention has interfered to some extent with the present research question. Unpublished results suggest that part of the C group continued to use products rich in polyunsaturated fat voluntarily. Hence, it was more difficult for the nutritional education programme to achieve a difference in saturated fat intake between I and C groups, and therefore to achieve an additional positive effect on serum lipids. Another limitation of the present study is that participants were not randomly allocated to I and C groups on an individual level. For example, the high proportion of users of antihypertensive medication in the I group may have limited the effects on blood pressure, since results

Table 3 Changes in risk factors and dietary intake after 3 years when compared to baseline, stratified for intervention condition (mean (SEM))

		Intervention n=80		Control n=119		p
Serum total cholesterol	(mmol/l)[a,b]	–0.28	(0.08)	–0.30	(0.1)	
Use of lipid-lowering drugs	(%)	12		11		
Diastolic blood pressure	(mm Hg)[c]	0.2	(1.4)	1.3	(1.1)	
Users of antihypertensive drugs excluded[d]		2.5	(2.5)	4.5	(1.8)	
Body weight	(kg)[b]	1.7	(0.5)	1.5	(0.4)	
Calculated CHD risk	(%)[a,b,e]	–0.3	(0.5)	–0.5	(0.4)	
Dietary intake						
Total fat	(% energy)[b]	–3.8	(0.7)	–1.8	(0.6)	<0.05
Saturated fatty acids	(% energy)[b]	–2.4	(0.3)	–1.3	(0.2)	<0.01
Dietary fibre	(grams/d)[b]	–0.1	(0.8)	–0.6	(0.6)	
Fish	(grams/d)[b]	12	(3)	1	(2)	<0.01
Fruit	(grams/d)[b]	0	(16)	–6	(12)	
Vegetables	(grams/d)[b]	11	(8)	–10	(6)	<0.0 5

a: Users of cholesterol lowering drugs during the study excluded; I group: n=73, C group: n=102.
b: Adjusted for baseline value and gender.
c: Adjusted for baseline value, gender, use of antihypertensive drugs at baseline.
d: I group: n=26, C group: n=50.
e: Calculated risk for a coronary heart disease (CHD) event within 10 years, using the Framingham risk equation.[13]

Table 4 Changes in risk factors and dietary intake after 3 years when compared to baseline, stratified for attendance at the meetings (mean (SEM))

		Intervention group			
		Attenders n=67		Non-attenders n=13	
Serum total cholesterol	(mmol/l)[a,b]	–0.36	(0.08)	0.01	(0.18)
Diastolic blood pressure	(mm Hg)[c]	1.1	(1.5)	–4.7	(3.8)
Body weight	(kg)[b]	1.9	(0.6)	0.6	(1.4)
Calculated CHD risk[d]	(%)[a,b]	–0.3	(0.4)	–0.2	(1.0)
Dietary intake		n=58		n=9	
Total fat	(% energy)[b]	–3.8	(0.7)	–4.7	(1.8)
Saturated fatty acids	(% energy)[b]	–2.4	(0.3)	–3.1	(0.9)
Saturated fatty acids ≤10% of energy	(%)	27%		20%	
Dietary fibre	(grams/d)[b]	0	(0.8)	–0.3	(2.0)
Fish	(grams/d)[b]	17	(3)	7	(8)
Fruit	(grams/d)[b]	–10	(14)	51	(37)
Vegetables	(grams/d)[b]	11	(11)	18	(28)

a: Users of cholesterol lowering drugs during the study excluded; att.: n=61, non-att.: n=12.
b: Adjusted for baseline value, gender, age.
c: Adjusted for baseline value, gender, age, use of antihypertensive drugs at baseline.
d: Calculated risk for a coronary heart disease (CHD) event within 10 years, using the Framingham risk equation.[13]

tended to be more positive in non-users (*table 3*). Finally, our population had a two to three times higher fruit consumption at baseline when compared with the average Dutch population.[16] This may indicate a 'ceiling effect' (the I group already ate sufficient fruit at baseline) or an invalid assessment of the intake. The difficulties in accurately assessing fruit and vegetables consumption are well known.[11] It should be noted, however, that 'ceiling effects' were also observed regarding the effects on intermediate effect parameters.[12] At baseline, 59% of I and C groups already belonged to the maintenance phase with regard to fruit consumption, and the scores on attitude, social norm and self-efficacy items all exceeded 5 (on a 6-point scale).[12] Regarding fish consumption, however, after 16 weeks positive effects were observed on the attitude, social norm, and intention. This is congruent with the long-term finding about increased fish intake in the I group.

Despite several limitations, these results are in agreement with other studies. After 3 years, Lovibond *et al*. found no additional positive effect on serum total cholesterol of an educational programme when compared to the posted leaflet.[17] Another study, with a shorter period of follow-up, found a 6% lower serum total cholesterol in the I group.[18] In this present study, besides the long period of follow-up, the lack of effect can also be partially explained by an insufficient difference in saturated fatty acids (SFA) intake between I and C groups (1.1% of energy). Other studies reduced SFA intake to a larger extent (2.4% of energy), and these studies significantly decreased serum total cholesterol (approximately 0.5 mmol/l).[19,20] Furthermore, the educational meetings did not reduce body weight, which would have enhanced positive effects on total cholesterol and blood pressure. It is known from the literature, however, that a more intensive approach is necessary to reduce weight,[21] which is difficult to incorporate in the usual care for persons at high cardiovascular risk.

In contrast to the established risk factors, the effects of the educational programme on dietary intake were positive. In particular the increased fish consumption in the I group is important because the cardioprotective effects of increased fish consumption are not primarily mediated by an effect on traditional risk factors but are due instead to an antiarrhythmic action.[22] Also the protective effects of a lower SFA intake are not completely mediated by traditional risk factors.[23] Hence, the changes in dietary behaviour (as established by the educational programme) lower CHD risk more than can be concluded at first sight from the effects on established risk factors (and hence the Framingham risk calculation). The present study, however, did not have sufficient power and/or period of follow-up to show an effect on cardiovascular events. Although the educational programme more effectively changed dietary behaviour than the posted leaflet, only 26% of the I group achieved the dietary goal of SFA intake below 10% of energy. It should be noted, however, that less than 10% of the general Dutch population (aged 50–65 years) has a SFA intake below 10% of energy[24] (a proportion which is similar to the C group).

In summary: the MARGARIN participants had a markedly increased risk for CHD (on average 15–16% over a 10 year time period) but nonetheless drug therapy (statins) in this group is not indicated according to the most recent guidelines.[6] Dietary therapy is an alternative and this data showed that a posted leaflet is not sufficient to change dietary behaviour. Intensive dietary counseling in groups by a dietician effectively increased fish consumption and decreased SFA intake over a 3 year period, and this is an encouraging result. However, no favourable effects were observed on the established CHD risk factors (compared to the C group) and the majority of the I group did not reach the guideline for SFA intake.

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